

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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OMB

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[Docket No. 00N-1674]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Addition of "Geriatric Use" Subsection in the Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Specific Requirements on Content and Format of Labeling for Human Prescription Drugs;
Addition of “Geriatric Use” Subsection in the Labeling (OMB Control No. 0910–0370)—
Extension**

Section 201.57(f)(10) (21 CFR 201.57(f)(10)) requires that the “Precautions” section of prescription drug labeling must include a subsection on the use of the drug in elderly or geriatric patients (aged 65 and over). The information collection burden imposed by this regulation is necessary to facilitate the safe and effective use of prescription drugs in older populations. The geriatric use subsection enables physicians to more effectively access geriatric information in physician prescription drug labeling.

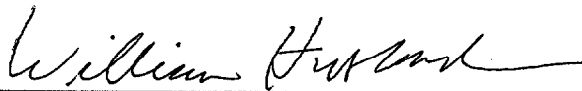
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents per Response	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
201.57(f)(10)—new drug applications	83	1.49	124	8	992
201.57(f)(10)—abbreviated new drug applications	117	3.96	464	2	928
Total					1,920

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

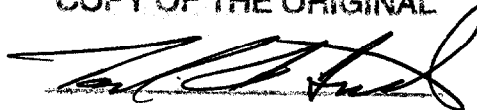
In the **Federal Register** of January 5, 2001 (66 FR 1142), the agency requested comments on the proposed collections of information. No significant comments were received.

Dated: 4/6/01
April 6, 2001.



William K. Hubbard,
Senior Associate Commissioner for Policy,
Planning, and Legislation.

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[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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